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EXAMINER

KISHORE, GOLLAMUDI S

| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,903

Applicant(s)

Huglin

Examiner

Gollamudi Kishore

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 29, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and amendment filed on 12-29-02 are acknowledged.

Claims included in the prosecution are 33-43.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 32-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What is conveyed in step c by “ and a lipophilic cosmetically active agent, in which any cosmetically active agent is lipophilic and always present as component c”?

Applicant’s arguments have been fully considered, but are not found to be persuasive. The very fact that applicant recites the presence of lipophilic cosmetically active agent along with the synthetic or natural triglyceride in the first instance in step c means that the lipophilic cosmetic agent must be present in this mixture. Therefore, the examiner questioned applicant’s intent of reciting again “any cosmetically active agent is lipophilic and always present as component c”. Applicant’s response does not address this issue.

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The independent claim 32 recites 'consisting essentially of' which rules out any additional steps; the various forms recited in the dependent claims 37-45 require additional steps and therefore, improper. In response to this rejection, applicant amends claims 37-45 to make them product claims. This will not solve the issue for the following reason. The method claim 32 recites on line 1, "a method of preparing a cosmetic formulation": In essence, this preamble defines the final formulation itself "in the form of an aqueous dispersion". The dependent claims recite the final form of the product as a stick, cream, gel etc. 'Consisting essentially of' in claim 32 and defining the cosmetic formulation as a nanodispersion will not permit the various forms of formulations recited in the dependent claims. The rejection, therefore, is maintained.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

4. Claims 32-43 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 349 150 of record.

EP discloses instant formulations and method of The formulations contain a phospholipid, a polyoxyethylene coemulsifier, an oil (triglyceride) and a lower alcohol, ethanol production (note pages 3-4, Examples and claims).

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that EP uses a homomixer. This argument is not found to be persuasive since according to instant claim, the step of adding the liquid in step alpha to a water phase is carried out in the absence of high shear or cavitational forces; a careful evaluation of EP's teachings indicate that homomixer is used after the addition of the water phase and therefore, the reference meets the requirements of instant claims.

5. Claims 32-43 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 711 557 or WO 96/37192, both are of record.

These patents disclose instant compositions and method of preparation(note the entire EP patent and the English equivalent 5,658,898); entire WO patent, in particular pages 5-6, 17, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that EP teaches the use of Rannie high-pressure homogenizer. However, the examiner is unable to determine from the reference as to at what step this homogenizer is used in the reference's teachings since there is no English translation. This rejection will be reconsidered, upon the submission of an English translation.

Applicant's arguments with regard to WO are not found to be persuasive. Applicant argues that WO teaches that for cosmetic formulations, ethanol, isopropanol or mixtures thereof may be optionally admixed as C2-C4 alkanol. It would appear that applicant has misinterpreted WO's teachings. Since ethanol is a C2 alcohol, it would appear that WO

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implies ethanol as C2 alkanol in cosmetic formulations and as applicant himself recognizes, WO teaches alkanol amounts which fall within the range claimed by applicant. With regard to applicant's arguments concerning the method steps, as applicant himself recognizes, the filtration and dialysis in the reference are optional.

5. Claims 32-43 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 0 852 941 or WO 97/21428 both are of record.

These patents disclose instant nanodispersions and the method of production (note the entire patents).

Upon consideration, the above rejections over EP (941) and WO 97 (428) have been withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 32-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0349150, or EP 0711557, or WO 96/37192 or WO 97/21428 cited above.

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The teachings of EP 0349150, EP 0711557 and WO 96/37192 have been discussed above.

WO 97/21428 discloses compositions containing a lipophilic active agent, fatty acid ester of polyoxyethylene sorbitan, a phospholipid, a triglyceride, ethanol and; the process involves mixing the lipophilic phase to the aqueous phase water (see pages 4-17 of the English equivalent, CA 2,238,263).

What is lacking in these references, is the teachings of the entire claimed range of the claimed components. However, it is deemed obvious to vary the amounts of the components of the prior art with the expectation of obtaining the best possible results since the prior art cited provides guidance to one of ordinary skill in the art as to how to prepare the compositions. WO 97 teaches 5 percent ethanol (page 15 of CA) which is slightly lower than the lower range claimed in instant claims. However, it is deemed obvious to vary the amounts of ethanol with the expectation of obtaining the best possible results since WO 97 provides guidance to one of ordinary skill in the art as to how to prepare the compositions

Applicant provides no specific arguments with regard to the 103 rejections and therefore, the rejections are maintained.

Note: EP 852 941 has been removed from the above 103 rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].


All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

February 19, 2003